

## REMARKS

Claims 1, 6-9, 11, 13, 15, 16, 65, 70-80, 90, 95-104, 138, 139, 141 and 143-189 are pending. Claims 1, 6-9, 11, 13, 15, 16, 65, 70-80, 90, 95-104, 138, 139, 141 and 144-189 are under examination. Claims 1, 65, 90, 138, 141 and 144 have been amended. Support for the amendments can be found throughout the specification and the claims as filed. In particular, support for the amendment to claims 1, 65, 90, 138, 141 and 144 to recite that the multidimensional space contains  $n$  axes, each of the axes relating to the expression level of a molecule of the  $n$  molecules, can be found, for example, in Figures 1 and 2 and page 3, line 22, to page 4, line 14, which show exemplary multidimensional analysis of 2 and 3 dimensions, respectively, with each axis relating to the expression level of a molecule. The amendment is further supported on page 66, lines 3-15, which indicates that a similar analysis can be applied in  $n$ -dimensional space higher than 2 or 3 dimensions. Accordingly, these amendments do not raise an issue of new matter and entry thereof is respectfully requested.

Rejection Under 35 U.S.C. § 101

The rejection of claims 1, 6-9, 11, 13, 15, 16 and 154-162 under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter is respectfully traversed. Applicants respectfully maintain that these claims are directed to statutory subject matter.

Applicants respectfully maintain that the claimed methods have a useful, concrete and tangible result. Referring to MPEP § 2106, the MPEP indicates that a claimed process is clearly statutory if it results in a physical transformation outside the computer, i.e., falls into one or both of the following specific categories,” referred to as “safe harbors” (MPEP § 2106 (IV)(B)(2)(b)). In particular, the MPEP states that “a statutory process is one that requires the measurements of physical objects or activities to be transformed outside of the computer into computer data (MPEP § 2106 (IV)(B)(2)(b)(i), under “Manipulation of Data Representing Physical Objects or Activities (Pre-Computer Process Activity)”). Referring to independent claim 1, the claim recites that the multidimensional coordinate point is representative of the expression levels of the  $n$  molecules in the individual. The expression levels are measured values, and Applicants respectfully submit that the claims, therefore, fall under the “safe harbor” and are directed to

statutory subject matter. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejection Under 35 U.S.C. § 112, Second Paragraph

The rejection of claims 1, 6-9, 11, 13, 15, 16, 65, 70-80, 90, 95-104, 138, 139, 141 and 144-189 under 35 U.S.C. § 112, second paragraph as allegedly indefinite is respectfully traversed. Applicants respectfully submit that the claims are clear and definite.

Independent claims 1, 65, 90, 138, 141 and 144 have been amended to recite, in step (a), creating a multidimensional space of  $n$  dimensions, wherein  $n$  represents the number of molecules being analyzed in a specimen from each individual in a population of reference individuals and wherein the multidimensional space contains  $n$  axes, each of the axes relating to the expression level of a molecule of the  $n$  molecules. This amendment merely provides further description of multidimensional space as recited in step (a). In the Office Action on page 3, it is stated that it is unclear whether “the expression levels of said  $n$  molecules” represented by a single “point” is intended to mean a single expression level of each of “ $n$ ” molecules of an individual or multiple expression levels of each of “ $n$ ” molecules of an individual. As recited in the claims, each point is determined in multidimensional space, where each axis of the multidimensional space relates to the expression level of a molecule of the  $n$  molecules. To illustrate this, Applicants refer to a simplified example of a multidimensional analysis as shown in Figure 1 (see also page 3, line 22, to page 4, line 4; page 64, line 1, to page 65, line 14). Figure 1 illustrates a multidimensional analysis having 2 dimensions, where each axis relates to the expression level of one molecule of the 2 molecules. The expression level of molecule 1 is plotted against the expression level of molecule 2 for an individual. Thus, each circle in Figure 1 represents a multidimensional coordinate point representative of the expression level of each of 2 molecules in an individual, shown in 2-dimensional space (page 3, line 22, to page 4, line 4).

The specification further teaches that multidimensional analysis can be performed with additional parameters, for example, in 3-dimensional space, as illustrated in Figure 2 (page 4, lines 5-14; page 65, line 15, to page 66, line 2). In Figure 2, each circle represents a multidimensional coordinate point representative of the expression level of each of 3 molecules in an individual, shown in 3-dimensional space, where each axis relates to the expression level of

one of the 3 molecules in an individual. The specification goes on to teach that, in addition to 2-dimensional and 3-dimensional analysis, a similar analysis can be applied in n-dimensional space, where n is the number of molecules in a sample of molecules (page 66, lines 3-15). Thus, a multidimensional coordinate point in multidimensional space is representative of the expression level of each of the n molecules analyzed in an individual, where each axis of multidimensional space relates to the expression level of a molecule of the n molecules. Referring specifically to the query in the Office Action, each "single point" is representative of the expression levels of n molecules, where the point represents the expression level for each of the n molecules.

Applicants respectfully submit that the claims are clear and definite. Accordingly, Applicants respectfully request that this rejection be withdrawn.

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. The Examiner is invited to call the undersigned agent if there are any questions.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP



Deborah L. Cadena

Registration No. 44,048

4370 La Jolla Village Drive, Suite 700  
San Diego, CA 92122  
Phone: 858.535.9001 DLC:llf  
Facsimile: 858.597.1585  
**Date: May 15, 2006**

**Please recognize our Customer No. 41552  
as our correspondence address.**